#### REMARKS

Reconsideration of the present application in view of the above amendments and following remarks is respectfully requested. Claims 1-16 are currently pending in the application. With this Amendment and Response, claims 10-16 are cancelled to expedite allowance of the subject application and without prejudice to the filing of any divisional, continuation, or continuation-in-part application thereon; claims 1, 5, 6, 8, and 9 are amended for clarity; and new claims 17-24 are added.

Claims 1, 5, 6, 8, and 9 are amended to more clearly define the subject matter encompassed by Applicants' invention. Claim 1 is amended to clarify the language of step (A) and to add the language "at least during the period when the pH of the mixture is lowered from 5 to 4.6" in step (B-1). Support for this amendment is found throughout the specification as filed, for example, on page 11, lines 20 to 25. Claims 5 and 6 are amended to replace the phrase "mixed material" with the term "mixture." Claim 8 is amended to add the language now found in steps (A), (B-1) and (C). Support for this amendment is found throughout the specification as filed, for example, on page 4, line 24 to page 7, line 1; page 11, lines 20-25; and page 14, lines 5-17. Claim 9 is amended to remove steps (A) and (B-1) and to incorporate step (B-2). Support for this amendment is found throughout the specification as filed, for example, at page 5, lines 9-21.

Support for new claims 17-24 may also be found throughout the specification as originally filed. For example, support for claim 17 may be found at page 6, lines 11-24; support for claim 18 may be found at page 14, lines 5-17; support for claim 19 may be found at page 7, lines 9-12; support for claim 20 may be found at page 11, lines 14-20; support for claim 21 may be found in Example 2, pages 20-22; support for claim 22 may be found at page 9, lines 12-23; support for claim 23 may be found at page 8, lines 17-20; support for claim 24 can be found at page 8, lines 20-26.

With the present amendments to claims 1, 5, 6, 8, and 9 and through the introduction of new claims 17-24, Applicants submit that no new matter has been added to the application. By the introduction of claims 17-24, and cancellation of claims 10-16, claims 1-9 and 17-24 are now pending in the application.

As a preliminary matter, Applicants note that on February 20, 2004 and on April 20,

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2004, respectively, Applicants submitted an Information Disclosure Statement (IDS) and a Supplemental IDS. Applicants respectfully request that the Examiner acknowledge that each of the references cited in the IDS and Supplemental IDS has been considered.

## PATENTABILITY UNDER 35 U.S.C. §112, FIRST PARAGRAPH

Claims 1, 6, 7, 9, 14, and 15 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly non-enabled by the specification.

Applicants note that, by the instant Amendment and Response, claims 14 and 15 are cancelled thereby obviating the present basis for rejection of these claims. Also, by this Amendment and Response, claims 1, 6, and 9 are amended for clarity and to further define the subject matter of the instant invention as set forth above.

The Examiner alleges that the microorganism strain, *Lactobacillus helveticus* CM4 FERM BP-6060 is required to practice the claimed invention. Accordingly, the Examiner states that the deposit requirement would be satisfied if Applicants provide assurances via affidavit or declaration, or by statement by an attorney of record, that (1) the specific strain has been deposited under the Budapest Treaty and (2) that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon granting of a patent.

Applicants note that *Lactobacillus helveticus* CM-4 FERM BP-6060 was deposited under the terms of the Budapest Treaty on August 15, 1997. *Lactobacillus helveticus* CM-4 FERM BP-6060 was deposited with the National Institute of Bioscience and Human-Technology Agency of Industrial Science and Technology in Japan, which is an International Depository Authority under the Budapest Treaty. Applicants enclose herewith a copy of the corresponding Deposit Receipt. Applicants believe that the deposit of *Lactobacillus helveticus* CM-4 FERM BP-6060 with an International Depository under the Budapest Treaty obviates each of the Examiner's present bases for rejection; submit that claims 1, 6, 7, 9, 14, and 15 are allowable under 35 U.S.C. §112, first paragraph; and respectfully request that the Examiner issue a Notice to that effect.

### PATENTABILITY UNDER 35 U.S.C. §102

Claims 1-6 and 9-14 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by EP Patent No. 583074 ("the '074 patent"), JP Patent No. 2782153 ("the '153 patent"), or US Patent No. 5,449,661 ("the '661 patent"). The Examiner alleges that these references teach (1) that *Lactobacillus helveticus* is mixed with skim milk to produce fermented milk, (2) that yeast can be added to the mixture as well, (3) that the viscosity of the milk is inherent to the milk, and (4) that "to mix" only requires combining into one mass.

As a preliminary matter, Applicants note that, by the present Amendment an Response, claims 10-14 are now cancelled thereby obviating the present bases for rejection of those claims. Claims 1, 5, 6 and 9 are amended as set forth above. Each of claims 2-6 and 9 depend from and contain each of the limitations of claim 1. Because none of the cited references contain each of the elements of claim 1, it necessarily follows that none of the cited references contain each of the elements of claims 2-6 and 9. Thus, the novelty of claims 2-6 and 9 necessarily flows from the novelty of claim 1.

Nonetheless, Applicants respectfully traverse the stated grounds for rejection under 35 U.S.C. §102(b) and submit that neither the `074 patent, the `153 patent, nor the `661 patent disclose each element of instant claims. Therefore, none of these references anticipate any of instant claims 1-6 and 9.

Claim 1, as presently amended, is directed to a method for producing fermented milk containing angiotensin converting enzyme inhibitory peptide. The method of claim 1 comprises the steps of (1) preparing a mixture of lactic acid bacteria and a starting material containing milk and (2) fermenting the mixture while stirring at least during the period when the pH of the mixture is lowered from 5 to 4, 6, so that curd pieces and whey are generated, whereby fermented milk containing said curd pieces and said whey containing the angiotensin converting enzyme inhibitory peptide is produced. As Applicants disclose in the specification, at pH 5, soft curds start to be generated in the mixture, and at pH 4.6, casein reaches its isoelectric point. By stirring the mixture at least over this pH range, the curd (precipitate) being formed is broken up into smaller pieces as it is formed, which further facilitates later separation of whey (supernatant) from the fermented milk.

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Applicants submit that neither the '074 patent, the '153 patent, nor the '661 patent disclose fermentation while stirring at least over the particular pH range as in the present invention. Furthermore, these references are silent about the advantage of such stirring to form smaller curd pieces and also to facilitate later separation of whey from the fermented milk. Thus, none of these references anticipate instant claim 1.

The Examiner alleges that "to mix" only requires combining into one mass. However, stirring has additional functions besides combining components into one mass. For example, stirring also functions to break up a mass into pieces. The references cited do not teach stirring over the particular pH range to break up a mass into pieces. And, as the Examiner concedes, neither the '074 patent, the '153 patent, nor the '661 patent disclose that whey can be recovered from fermented milk.

The Examiner also alleges that the viscosity of the milk is inherent to the milk. The viscosity referred to in claims 3 and 20 is not, however, of the milk in the starting material but, rather, the viscosity results from fermenting the starting material mixture while stirring at least over the particular pH range. By fermenting the starting material mixture while stirring at least over the particular pH range, the viscosity of the resulting fermented milk is lowered. The viscosity of the resulting fermented milk is not inherent to the fermented milk, but results from stirring under particular conditions.

Applicants respectfully submit that the instant claims distinguish patentably over the disclosures of the '074 patent, the '153 patent, and the '661 patent as required under 35 U.S.C. §102(b). Therefore, Applicants request that this rejection be withdrawn and that the Examiner issue a Notice to that effect.

Claims 1-4, 6, 8-12, 14 and 16 stand rejected under 35 §102(b) as allegedly anticipated by Yamamoto et al. '796 ("the '796 patent") or Yamamoto et al. '111 ("the '111 patent"). The Examiner alleges that these references teach that Lactobacillus helveticus is mixed with skim milk to produce fermented milk. According to the Examiner, the fermented milk inherently contains the peptide since the same starting materials are used and since the process is the same. The Examiner further alleges that the viscosity of the milk is inherent to the milk. Finally, the Examiner asserts that "to mix" only requires combining into one mass.

As a preliminary matter, Applicants note that, by the present Amendment and Response, claims 10-16 are cancelled thereby obviating the present bases for rejection as to those claims. Claims 1, 6, 8, and 9 are amended as set forth above. Each of claims 2-4, 6, 8, and 9 depend from and contain each of the limitations of claim 1. Because none of the cited references contain each of the elements of claim 1, it necessarily follows that none of the cited references contain each of the elements of claims 2-4, 6, 8, and 9. Thus, the novelty of claims 2-4, 6, 8, and 9 necessarily flows from the novelty of claim 1.

Nonetheless, Applicants respectfully traverse the stated grounds for rejection under 35 U.S.C. §102(b) and submit that neither the `796 patent nor the `111 patent disclose each element of instant claims. Therefore, none of these references anticipate any of instant claims 1-4, 6, 8, and 9.

Applicants submit that neither of the `796 and '111 patents teach fermentation while stirring at least over the particular pH range as in the present invention. Furthermore, the references cited by the Examiner are silent about stirring to form smaller curd pieces and also to facilitate later separation of whey from the fermented milk.

Accordingly, Applicants respectfully submit that the instant claims distinguish patentably over the '796 and '111 patents and, therefore, satisfy the requirements of 35 U.S.C. §102(b). Applicants request that this rejection be withdrawn and that the Examiner issue a Notice to that effect.

#### PATENTABILITY UNDER 35 U.S.C. §103

Claims 1-16 stand rejected under 35 U.S.C. §103(a) as allegedly obvious over the '074 patent, the '153 patent, or the '661 patent in view of either the '796 patent or the '111 patent. The Examiner concedes that none of the primary references teach using the specific strain Lactobacillus helveticus CM4 FERM BP-6060, but alleges that it, nevertheless, would have been obvious to use such a strain since such strains were well known in the art. The Examiner alleges that the strain disclosed in the cited references would be expected to produce the same enzyme inhibitor as that produced by Lactobacillus helveticus CM4 FERM BP-6060. The Examiner notes that none of the '074, '153, or '661 patents teach that whey can be recovered from fermented milk,

but alleges that `796 patent or the `111 patent overcome that deficiency by teaching the recovery of whey from fermented milk.

Claims 1-16 also stand rejected under 35 U.S.C. §103(a) as obvious over the '796 patent or the '111 patent in view of either the '074 patent, the '153 patent, or the '661 patent. The Examiner concedes that the cited references do not teach using the specific strain *Lactobacillus helveticus* CM4 FERM BP-6060. The Examiner alleges, however, that it would have been obvious to use such a strain since such strains are well known in the art. The Examiner alleges that the strain disclosed in the cited references would be expected to produce the same enzyme inhibitor as that produced by *Lactobacillus helveticus* CM4 FERM BP-6060. The Examiner also concedes that neither the '796 patent nor the '111 patent teach using yeasts along with bacteria to produce fermented milk, but alleges that it would have been obvious to use yeasts along with the claimed bacteria to produce fermented milk in view of the '074 patent, the '153 patent, or the '661 patent.

As a preliminary matter, Applicants note that, by the present Amendment and Response, claims 10-16 are cancelled thereby obviating the present basis for rejection of these claims. Claims 1, 5, 6, 8, and 9 are amended as set forth above. Each of claims 2-9 depend from and contain each of the limitations of claim 1. Because the cited references, viewed as a whole, fail to teach or suggest each of the elements of claim 1, it necessarily follows that none of the cited references teach or suggest each of the elements of claims 2-9. Thus, the nonobviousness of claims 2-9 necessarily flows from the nonobviousness of claim 1.

Nonetheless, Applicants respectfully traverse the stated grounds for rejection of instant claims 1-9. More specifically, none of these references teach fermentation while stirring at least over the particular pH range as in the present invention. Furthermore, these references are silent about stirring either (a) to form smaller curd pieces or (b) to facilitate later separation of whey from the fermented milk.

Accordingly, Applicants respectfully submit that the instant claims distinguish patentably (1) over the '074 patent, the '153 patent, or the '661 patent in view of either the '796 patent or the '111 patent or (2) over the '796 patent or the '111 patent in view of either the '074 patent, the '153 patent, or the '661 patent. Applicants therefore submit that the instant claims

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satisfy the requirements of 35 U.S.C. §103(a), that the present bases for rejection be withdrawn, and that the Examiner issue a Notice to that effect.

# **CONCLUSION**

All of the claims pending in the application are now believed to be allowable. Favorable consideration and a Notice of Allowance are earnestly solicited. The Examiner is urged to contact the undersigned attorney if there are any questions prior to allowance of this matter. In view of the above amendment, applicant believes the pending application is in condition for allowance.

Dated: March 7, 2006

Respectfully submitted,

Gary M. Myles, Ph.D. Registration No.: 46,209

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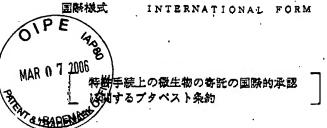
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Attorneys/Agents For Applicant

国際様式



下記国際委託当局によって規則7,1に従い 発行される。

原寄託についての受託証。

BUDAPEST TREATY ON THE INTERNATIO-NAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT

issued pursuant to Rule 7.1 by the INTERNATIONAL DEPOSITARY AUTHORITY identified at the bottom of this page.

氏名(名称)

カルピス食品工業株式会社 代表取締役 小林 公生

等託者

あて名 **T** 150

東京都渋谷区恵比券西2-20-3

殿

1. 機生物の表示

(寄託者が付した職別のための表示)

ラクトパチルス・ヘルペチカス CM-4 (Lactobacillus Helvaticus CM-4) (受託番号) FERM BP- 6060

- 2. 科学的性質及び分類学上の位置
  - 1 欄の撤生物には、次の事項を記載した文書が続付されていた。
    - 科学的性質
    - 分類学上の位置
- 3. 受領及び受託

本国際客託当局は、 平成 9年 8月15日(原客託日)に受領した1欄の微生物を受託する。

4. 移管請求の受領

本国際各託当局は、

月 日(原客託日)に1欄の微生物を受領した。

そして、 日 に原寄託よりブダベスト条約に基づく寄託への移管請求を受領した。

5、国際寄託当局

通商產業省工業技術院生命工学工業技術研究所

of Bioscience and Human-Technology

Science and Technology

Michie D DIRECTOR GENERAL.

あて名: 日本国茨 市東1丁目1番3号(郵便番号305)

1-3,.Higash ukub'a-shi Ibaraki-ken 305, JAPAN

平成 9年(1997) 8月15日



BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

RECEIFT IN THE CASE OF AN ORIGINAL DEPOSIT issued pursuant to Rule 7.1 by the INTERNATIONAL DEPOSITARY AUTHORITY identified at the bottom of this page

To Depositor: Name - The Calpis Food Industry Co., Ltd.
Kimio KOBAYASHI, Director-Representative

Address - 20-3, Ebisu-Nishi 2-chome, Shibuya-ku, Tokyo 150

1. Name of Microorganisms:

(Name for Identification given by Depositor) Lactobacillus helveticus CM-4

(Accession Number) FERM BP- 6060

2. Scientific Description and Taxonomic Designation:

A written statement describing the following information was appended to the microorganism of Section I.

Scientific Description - Yes
Taxonomic Designation - Yes

3. Acknowledgement and Receipt:

The present International Depositary Authority has accepted the deposit of the microorganism in Section I acknowledged on August 15, 1997 (the date of an original deposit).

- 4. Acknowledgement of Petition for Conversion:
- 5. International Depositary Authority:

Name - National Institute of Bioscience and Human-Technology Agency of Industrial Science and Technology, Ministry of International Trade and Industry Michio OISHI, Ph. D., Director General

Address - 1-3, Higashi 1 chome, Tsukuba-shi, Ibaraki-ken, 305 Japan.

(SEAL)

Dated: August 15, 1997